SEP 3 1996

## SAFETY AND EFFECTIVENESS SUMMARY K962935

**COMMON/USUAL NAME:** Electrosurgical Electrode

**PROPRIETARY NAME:** ***unimed*** Coated Needle Electrode, ***unimed*** Coated Blade Electrode, and ***unimed*** Coated Ball Electrode

**CLASSIFICATION:** CLASS II

**MATERIALS:** All materials used to manufacture the Coated Electrodes are non-toxic and have been used in previously marketed devices.

DESCRIPTION:

The Coated Electrodes are coated with Emralon 333 or Teflon 420-104. Both are dry lubricants which provide a low coefficient of friction and reduce eschar build-up during surgery and the need for higher power settings. Without eschar build-up that takes place with a standard stainless steel tip less scraping and inconvenience takes place resulting in greater OR efficiency.

Emralon and Teflon are non-toxic, corrosion resistant, and therefore safe for the patient and the OR staff.

The Coated Electrosurgical Electrodes are available in a variety of tip configurations and lengths. The tip configurations include blades, needles, and balls. The blades and needles are also available with the tips only partially exposed.

These devices are designed to cut and coagulate soft tissue during surgical procedures. The entire line of electrodes will fit all button, rocker, and foot-controlled pencils. The electrodes are available sterile, single use only.

**SUBSTANTIAL EQUIVALENCE:** ***unimed's*** electrodes are currently sold in the USA under numerous proprietary names by other medical device companies. ***unimed*** Surgical Products, Inc. is presently a component supplier of these parts. ***unimed*** Surgical Products, Inc. now wants to market these devices under its own trade name, as well as maintain the component supplier status.